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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,545	07/02/2008	Hidetsugu Takagaki	060750	3545
21874	7590	03/18/2009		
EDWARDS ANGELL PALMER & DODGE LLP			EXAMINER	
P.O. BOX 55874			NWAONICHA, CHUKWUMA O	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1621	
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			03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,545	Applicant(s) TAKAGAKI ET AL.	
	Examiner CHUKWUMA O. NWAONICHA	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/14, 9/26 & 9/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Current Status

1. Claims 1-22 are under active consideration in the instant application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the variable X is defined as an anion capable of forming a salt with a quaternary ammonium group. It is not clear which anion Applicants are claiming. Claim 15, 16 and 19 are rejected because the claims recite "therapeutic agent". It is not clear if Applicants are claiming a compound or a composition. Claim 18 and 21 are rejected because the claims recite "treatment method" without setting forth any steps involved in the process. Appropriate corrections are required.

Claims 17 and 20 are provides for the use of compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

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merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17 and 20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

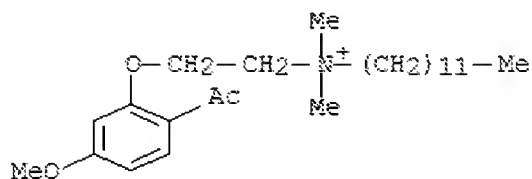
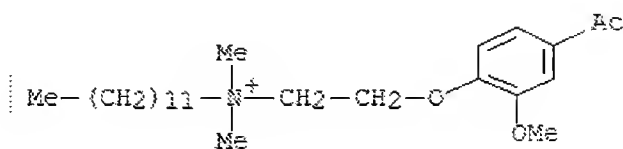
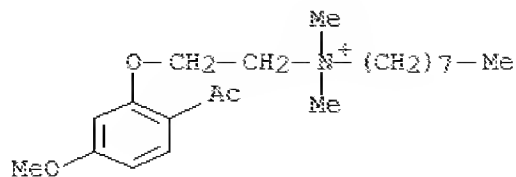
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Pierre et al., {US 3,801,641}.

Pierre et al. disclose applicant's claimed quaternary ammonium compounds as shown below and a process of preparing quaternary ammonium compounds in the presence of and acid or a synthetic resin anion exchanger.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copp et al., {GB 9 19,126} in view of Pierre et al., {US 3,801,641}.

Applicant claims a quaternary ammonium compound, a process of preparing quaternary ammonium compound in the presence of an acid or an ion exchange resin, cerebrovascular disease therapeutic agent and a method of treating cerebrovascular disease therapeutic agent; wherein all the other variables are as defined in the claims.

Determination of the scope and content of the prior art (M.P.E.P. §2141.01)

Copp et al. teach a quaternary ammonium compound, a process of preparing quaternary ammonium compound in the presence of organic solvent including alcohol; wherein all the other variables are as defined in the specification. See pages 1-3.

Ascertainment of the difference between the prior art and the claims (M.P.E.P. §2141.02)

Copp et al. quaternary ammonium compound and the process of making the same differ from the instantly claimed quaternary ammonium compound and the process of making the same in that applicants claim a process wherein an ion exchange

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resin and sulfur compound are employ while Copp et al.'s is silent about an ion exchange resin and sulfur compound.

However, the secondary reference of Pierre et al. teaches a quaternary ammonium compound, a process of preparing quaternary ammonium compound in the presence of an acid, a synthetic resin anion exchanger and wherein sulfur compound is employed. See columns 5 and 6.

Finding of prima facie obviousness--rational and motivation (M.P.E.P.. §2142-2143)

The instantly claimed quaternary ammonium compound, the process of making the same and a method for treating cerebrovascular disease with a quaternary ammonium compound would have been suggested to one of ordinary skill because one of ordinary skill wishing to obtain a quaternary ammonium compound is taught to select the quaternary ammonium compounds and process for making the same from the teaching of Copp et al. and Pierre et al.

One of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention by varying the substituents of the genus of Copp et al. and Pierre et al. to arrive at the instantly claimed quaternary ammonium compound and the process of making the same. Said person would have been motivated to practice the teaching of the reference cited because it demonstrates that quaternary ammonium compounds have industrial and pharmaceutical applications.

Moreover, all the claimed elements were known in the prior art references cited and one skilled in the art could have combined the elements as claimed by known methods

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with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The instantly claimed invention would therefore have been obvious to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chukwuma O. Nwaonicha/
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/Karl J. Puttlitz/

Primary Examiner, Art Unit 1621